



06-29-07

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Attorney's Docket No.: 17118-056002 / 2835B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gevas et al.
Serial No. : 10/762,226
Filed : January 20, 2004

Art Unit : 1642
Examiner : Susan Ungar, Ph.D.
Cust. No. : 20985
Conf. No. : 2197

Title : IMMUNOLOGICAL METHODS FOR THE TREATMENT OF
GASTROINTESTINAL CANCER

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

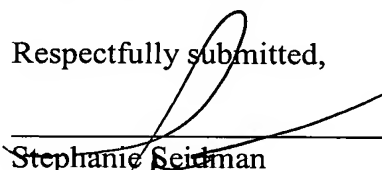
Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Form PTO-1449 (5 pages), copies of two U.S. Office Actions, copies of two European Examination Reports, cited non U.S. patent documents listed on the form PTO-1449, and a return postcard for filing in connection with the above-captioned application. Because this Supplemental Information Disclosure Statement is filed with a Request for Continued Examination and prior to receipt of a first Office Action on the merits for the above-captioned application, a fee for filing this statement should not be due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:



The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,


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Stephanie Seidman



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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

This Supplemental Information Disclosure Statement is filed with a Request for Continued Examination of the above-captioned application and prior to receipt of an Office Action. Thus, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (5 pages) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

In accordance with the requirements of 37 C.F.R. §1.98, provided herewith and submitted for consideration by the Examiner is a copy of a U.S. Office Action (Document I), issued June 24, 1998, in connection with U.S. Patent Application No. 08/798,423 (Attorney Docket No. 17118-056001/2835). Also provided herewith is a copy of a European

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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

Stephanie Spidman

Examination Report (Document II), issued September 17, 2003, in connection with European Patent Application No. 97905858.3 (Attorney Docket No. 17118-056EP1/2835EP), which is a national stage filing of International Patent Application No. PCT/US97/02029, which claims priority to U.S. Provisional Application Serial No. 60/011,411. The instant application is a continuation of U.S. Patent Application No. 08/798,423, which claims priority to U.S. Provisional Application Serial No. 60/011,411.

Also provided herewith and submitted for consideration by the Examiner is a copy of a U.S. Office Action (Document III), issued August 9, 2006, in connection with U.S. Patent Application No. 08/462158 (Attorney Docket No. 17118-054US3/2833CUS). In the Office Action, Examiner cited five documents: 1) US 4,526,716; 2) Bowie *et al.*, "Deciphering the message in protein sequences: Tolerance to amino acid substitutions" *Science* 247:1306-1310 (1990); 3) Houghton *et al.*, "Relative importance of position and individual amino acid residues in peptide antigen-antibody interactions: Implications in the mechanism of antigenic drift and antigenic shift" *Vaccine* 86:21-25 (1986); 4) Iwanaga *et al.*, "Immunocytochemical localization of the different gastrin forms in the pyloric antrum" *Biomed. Res.* 1:316-320 (1980); and 5) Siemann, "Satisfactory and unsatisfactory tumor models: Factors influencing the selection of a tumor model for experimental evaluation", *Rodent Tumor Models in Experimental Cancer Therapy* (Ed. Kallman) Pergamon Press, NY: 12-15 (1987). Also provided herewith is a copy of a European Examination Report (Document IV), issued November 18, 2003, in connection with European Patent Application No. 99921972.8 (Attorney Docket No. 17118-061EP1/2840EP). In the European Examination Report, Examiner cited 4 documents: D1) EP 0755683, D2) Ajani *et al.*, "Phase I and II Studies of the Combination of Recombinant Human Interferon- and 5-Fluorouracil in Patients with Advanced Colorectal Carcinoma" *J. Biol. Response Mod.* 8(2):140-146 (1989); D3) Watson *et al.*, "Anti-gastrin antibodies raised by gastrimmune inhibit growth of colorectal tumor AP5" *Int. J. Cancer*, 61(2):233-240 (1995); and D4) EP 0380230.

The table below lists Documents I-IV and includes a column that provides a space next to the document to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document
	I	Copy of Office Action, issued June 24, 1998, in connection with U.S. Patent Application No. 08/798,423

Examiner Initial	Document No.	Document
	II	Copy of Examination Report, issued September 17, 2003, in connection with European Patent Application No. 97905858.3
	III	Copy of Office Action, issued August 9, 2006, in connection with U.S. Patent Application No. 08/462158
	IV	Copy of Examination Report, issued November 18, 2003, in connection with European Patent Application No. 99921972.8

Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
09/700,402	12/04/01	17118-061US1/ 2840US
11/360,378	02/22/06	17118-062002/ 2841B
11/499,261	08/03/06	17118-064003/ 2843C
11/808,889	05/07/07	17118-064004/ 2843D
11/659,937	02/09/07	17118-066US1/ 2845US
11/663,126	03/16/07	17118-067US1/ 2846US
11/036,690	01/14/05	17118-073003/ 2849C
11/489,775	07/20/06	17118-073004/ 2849D
11/492,695	07/25/06	17118-073005/ 2849E

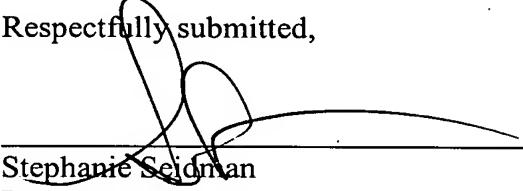
Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97 (g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56 (b) exists.

Applicant : Gevas *et al.*
Serial No. : 10/762,226
Filed : January 20, 2004

Attorney's Docket No.: 17118-056002 / 2835B
Supplemental Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing documents and make them of record in the file history of the above-captioned application.

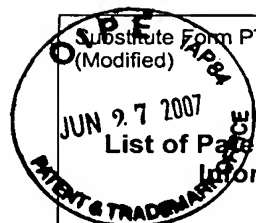
Respectfully submitted,



Stephanie Seidman
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 Substitute Form PTO-1449
(Modified)

 U.S. Department of Commerce
Patent and Trademark Office

 Attorney's Docket No.
17118-056002/2835B

 Application No.
10/762,226

**List of Patents and Publications for Applicant's
Information Disclosure Statement**

 Applicant
Gevas et al.

 Filing Date
January 20, 2004

 Group Art Unit
1642

(37 CFR §1.98(b))

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2005/0169979	08/04/05	Michaeli et al.	424	184.100	01/14/05
	AB	2007/0065454	03/22/07	Michaeli et al.	424	184.1	07/20/06
	AC	2007/0082043	04/12/07	Michaeli et al.	424	184.1	07/25/06
	AD	3,931,141	01/06/76	Wissmann	530	329	11/15/73
	AE	4,302,386	11/24/81	Stevens	260	112.5	04/15/85
	AF	4,565,805	1/21/86	Smirnov	514	17	11/20/84
	AG	4,794,103	12/27/88	Bertolini	514	012	01/02/87
	AH	5,843,446	12/01/98	Ladd et al.	424	184.1	06/07/95
	AI	6,815,414	11/09/04	Chowers et al.	514	008	12/15/00

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AJ	01/34192	05/17/01	PCT				
	AK	06/008649	01/26/06	PCT				
	AL	06/016275	02/16/06	PCT				
	AM	06/032980	03/30/06	PCT				
	AN	95/21380	08/10/95	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AO	Abrahm et al., "Development and evaluation of a high affinity species and region specific monoclonal antibody to human gastrin," Gastroenterology, 86(5(2)):1012, (1984).
	AP	Beacham et al., "Human Gastrin: Isolation, Structure and Synthesis: Synthesis of Human Gastrin I", Nature 209(5023):585-586, (1966).
	AQ	Bentley et al., "Human Gastrin: Isolation, Structure and Synthesis: Structures of Human Gastrins I and II" Nature 209(5023):583-585, (1966).
	AR	Bowie et al., "Deciphering the message in protein sequences: Tolerance to amino acid substitutions," Science, 247:1306-1310, (1990).
	AS	Bystry, J., "Tumor vaccines," Cancer and Metastasis Reviews, 9:81-91, (1990).
	AT	Caplin et al., "Serum gastrin levels and identification of CCK-B-gastrin receptor following partial hepatectomy for liver tumours in man," Gastroenterology, 110(4 suppl.) A1162, (1996).

Examiner Signature

Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 17118-056002/2835B		Application No. 10/762,226	
List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b))				Applicant Gevas et al.			
				Filing Date January 20, 2004		Group Art Unit 1642	
Other Documents (include Author, Title, Date, and Place of Publication)							
Examiner Initial	Desig. ID	Document					
	AU	Caplin et al., "Expression and processing of gastrin in patients with hepatocellular carcinoma, fibrolamellar carcinoma and cholangiocarcinoma," Gastroenterology 114(Supplement 1): A1219 (Abstract # L0083) (April 15, 1998).					
	AV	Caplin et al., "Expression and processing of gastrin in patients with pancreatic carcinoma," Gastroenterology 114(Supplement 1): A445 (Abstract # G1809) (April 15, 1998).					
	AW	Choudhury et al., "N-Terminal sequence of human big gastrin: Sequence, synthetic and immunochemical studies," A76 Hoppe-Seyler's Z. Physiol. Chem., 361:1719-1733, (1980).					
	AX	Del Valle et al., "Progastrin and its glycine-extended posttranslational processing intermediates in human gastrointestinal tissues," Gastroenterology, 92:1908-1912, (1987).					
	AY	Dickinson et al., "Gastrin-amidating enzyme in the porcine pituitary and antrum" J. Biol. Chem., 266:334-338, (1991).					
	AZ	Dockray et al., "Heptadecapeptide gastrin: measurement in blood by specific radioimmunoassay," Gastroenterology, 71(6):971-977, (1976).					
	BA	Dockray et al., "Immunochemical studies on big gastrin using NH2-terminal specific antisera," Chemical Abstracts, 94:506-507, (1981) [Abstract #94:119200w].					
	BB	Dockray et al., "Immunochemical studies on big gastrin using NH2-terminal specific antisera," Regulatory Peptides, 1:169-186, (1980).					
	BC	Gregory et al., "Isolation of two gastrins from human antral mucosa," Nature, 209(5023):583, (1966).					
	BD	Halter et al., "Evaluation of a monoclonal anti-gastrin antibody as a tool for immunoneutralization of gastrin during omeprazole treatment in the rat," Gastroenterology, 96(5) part 2:A194, (1989).					
	BE	Houghton et al., "Relative importance of position and individual amino acid residues in peptide antigen-antibody interactions: Implications in the mechanism of antigenic drift and antigenic shift," Vaccine, 86:21-25, (1986).					
	BF	Hughes et al., "Therapy with gastrin antibody in the Zollinger-Ellison syndrome," Digestive Diseases, 21:201-204, (1976).					
	BG	Iwanaga et al., "Immunocytochemical localization of the different gastrin forms in the pyloric antrum," Biomed. Res., 1:316-320, (1980).					
	BH	Iwase et al., "Regulation of growth of human gastric cancer by gastrin and glycine-extended pro-gastrin," Gastroenterology, 113:782-790, (1997).					
	BI	Jaffe et al., "Inhibition of endogenous gastrin activity by incubation with antibodies to the C-terminal tetrapeptide of gastrin," Surgery, 65:633-639, (1969).					
	BJ	Jaffe et al., "Inhibition of gastrin activity with antibodies to C-terminal tetrapeptide of gastrin," Surgery, 65(4):633-639, (1969).					
	BK	Joshi et al., "Gastrin and colon cancer: a unifying hypothesis," Digestive Diseases, 14:334-344, (1996).					
	BL	Justin, T. and R. Steele et al., "Gastric acid suppression using anti-gastrin 17 antibodies produced by a gastrin immunogen, Gastrimmune, in an in vivo pig model," Gastroenterology, 108(4):A125, (1995).					
	BM	Koh et al., "Glycine-extended gastrin promotes the growth of a human hepatoma cell line," Gastroenterology, 110(4):1089, (1996).					
	BN	Kohler et al., "Continuous cultures of fused cells secreting antibody of predefined specificity," Nature, 256:495-497, (1975).					
Examiner Signature				Date Considered			
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Other Documents (include Author, Title, Date, and Place of Publication)							
Examiner Initial	Desig. ID	Document					
	BO	Kothary et al., "Identification of gastrin molecular variants in gastrinoma syndrome," Regulatory Peptides 17:71-84, (1987).					
	BP	Kovacs et al., "Gastrin partially mediates insulin-induced acid secretion in dogs," Peptides, 17(4):583-587, (1996).					
	BQ	Kusyk et al., "Stimulation of growth of a colon cancer cell line by gastrin," Am. J. Physiol., 251:G597-G601, (1986).					
	BR	Lamers et al., "Role of gastrin and cholecystokinin in tumors of the gastrointestinal tract," Eur. J. Cancer Clin. Oncol., 24(2):267-273, (1988).					
	BS	Lamote et al., "Stimulating effect of pentagastrin on cancer cell proliferation kinetics in chemically induced colon cancer in rats," Regulatory Peptides, 20:1-9, (1988).					
	BT	Larsson et al. "Characterization of antral gastrin cells with region-specific antisera," J. Histochem. Cytochem., 25:1317-1321, (1977).					
	BU	Makishima et al., "Active immunization against gastrin-17 with an N-terminal derived immunogen inhibits gastric and duodenal lesions in rats," Gastroenterology, 106(4/2):A824, (1994) [Abstract].					
	BV	Makishima et al., "Inhibition of Gastrin-17 Stimulated acid secretion through active immunization in rats," FASEB J. 8:A92, Abs. 535, (1994).					
	BW	McGregor et al., "Trophic effects of gastrin on colorectal neoplasms in the rat", Ann. Surg., 195(2):219-223, (1982).					
	BX	McWilliams et al., "Coexpression of Gastrin and Gastrin Receptors (CCK-B and CCK-B) in gastrointestinal tumour cell lines," Gut, 42:795-798, (1998).					
	BY	Mu et al., "Monoclonal antibody to the gastrin receptor on parietal cells recognizes a 78-kDa protein," Proc. Natl. Acad. Sci., 84:2698-2702, (1987).					
	BZ	Negre et al., "Autocrine stimulation of AR4-2J rat pancreatic tumour cell growth by glycine-extended gastrin," Int. J. Cancer, 66(5):653-658, (1996).					
	CA	Ochiai et al., "Growth-promoting effect of gastrin on human gastric carcinoma cell line TMK-1," Japan J. Can. Res., 76:1064-1071, (1985).					
	CB	Ohkura et al., "Gastrin-enhanced tumor growth of a xenotransplantable human gastric carcinoma in nude mice," Jpn. J. Clin. Oncol., 10(2):255-263, (1980).					
	CC	Ohning et al., "Gastrin mediates the gastric mucosal proliferative response to feeding," American Journal of Physiology, 271(3(1)):G470-G476, (1996).					
	CD	Okada et al., "Evaluation of cholecystokinin, gastrin, CCK-A receptor and CCK-B/gastrin receptor gene expressions in gastrin cancer," Cancer Letters, 106(2):257-262, (1996).					
	CE	Palnaes et al., "Metabolism and influence of glycine-extended gastrin on gastric acid secretion in man," Digestion, 57:22-29, (1996).					
	CF	Power et al., "A novel gastrin-processing pathway in mammalian antrum," Chemical Abstracts, 109(9):113, (1988) [Abstract #109:67341z].					
	CG	Rahier et al., "Biosynthesis of Gastrin. Localization of the recursor and peptide products using electron microscopic-immunogold methods," Gastroenterology, 92:1146-1152, (1987).					
	CH	Rehfeld et al., "Gastrin in human bronchogenic carcinomas: constant expression but variable processing of progastrin," Cancer Res., 49:2840-2843, (1989).					
	CI	Romani et al. "Gastrin receptor antagonist CI-988 inhibits growth of human colon cancer in vivo and in vitro," AZN J. Surgery, 66:235-237, (1996).					

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	CJ	Seva et al., "Characterization of the glycine-extended gastrin (G-gly) receptor on AR 42Z cells," <i>Gastroenterology</i> , A1005, (1995).					
	CK	Siemann, "Satisfactory and unsatisfactory tumor models: Factors influencing the selection of a tumor model for experimental evaluation", <i>Rodent Tumor Models in Experimental Cancer Therapy</i> (Ed. Kallman) Pergamon Press, NY: 12-15, (1987).					
	CL	Singh et al., "Hormones in colon cancer: past and prospective studies," <i>Cancer J.</i> , 3:28-33, (1990).					
	CM	Singh et al., "Incomplete processing of progastrin expressed by human colon cancer cells: roles of noncarboxyamidated gastrins," <i>Journal of the American Physiological Society</i> , G459-G468, (1994).					
	CN	Singh et al., "Novel gastrin receptors mediate mitogenic effects of gastrin and processing intermediates of gastrin on Swiss 3T3 fibroblasts. Absence of detectable cholecystokinin (CCK)-A and CCK-B receptors," <i>J. Biol. Chem.</i> , 270:8429-8435, (1995).					
	CO	Singh et al., "Role of gastrin and gastrin receptors on the growth of a transplantable mouse colon carcinoma (MC-26) in BALB/c Mice," <i>Cancer Res.</i> , 46:1612-1616, (1986).					
	CP	Smith et al. "Gastrin regulates the growth of human pancreatic cancer in a tonic and autocrine fashion," <i>Amer. J. Physiol.</i> , 270(5):R1078-R1084, (1996).					
	CQ	Smith et al. "Identification of gastrin as a growth peptide in human pancreatic cancer," <i>Amer. J. Physiol.</i> , 268:R135-R141, (1995).					
	CR	Smith et al., "Effects of gastrin, proglumide, and somatostatin on growth of human colon cancer," <i>Gastroenterology</i> , 95(6):1541-1548 (1988).					
	CS	Sobhani et al., "Immunohistochemical characterization of gastrinomas with antibodies specific to different fragments of progastrin," <i>Gastroenterol. Clin. Biol.</i> , 13:865-872, (1989).					
	CT	Stepan et al., "Glycine-extended gastrin exerts growth-promoting effects on colon cancer cell lines," <i>Mol. Med.</i> , 5(3):147-159, (1999).					
	CU	Tarasova et al., "Endocytosis of gastrin in cancer cells expressing gastrin/CCK-B receptor," <i>Cell and Tissue Research</i> , 287:325-333, (1997).					
	CV	Varro et al., "Pathways of processing of the gastrin precursor in rat antral mucosa," <i>J. Clin. Invest.</i> , 95:1642-1649, (1995).					
	CW	Watson et al., "A hepatic invasive human colorectal xenograft model," <i>Eur. J. Cancer</i> , 29(12):1740-1745, (1993).					
	CX	Watson et al., "Detection of gastrin receptors on gastrointestinal tumors using the anti-gastrin receptor monoclonal antibody, 2CL," <i>Gut</i> , 4:F271, (1993).					
	CY	Watson et al., "Expression of gastrin-CCKB receptor isoforms in gastrointestinal tumor cells," <i>Int. J. Cancer</i> , 77(4):572-577, (1998).					
	CZ	Watson et al., "Gastrin antagonists in the treatment of gastric cancer," <i>Anticancer Drugs</i> 4(6):599-604, (1993).					
	DA	Watson et al., "The effect of the E2 prostaglandin enprostil, and the somatostatin analogue sms201995, on the growth of a human gastric cell line, MKN45G," <i>Int. J. Cancer</i> , 45:90-94, (1990).					
	DB	Watson et al., "Gastrin: growth promoting effects on human gastric and colonic tumour cells," <i>Br. J. Cancer</i> , 59:554-558, (1989).					
	DC	Watson, S.A., et al., "Gastrin: growth enhancing effects on human gastric and colonic tumour cells," <i>British Journal of Surgery</i> , 75(4):342-345, (1988).					

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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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				Filing Date January 20, 2004	Group Art Unit 1642
				Other Documents (include Author, Title, Date, and Place of Publication)	
Examiner Initial	Desig. ID	Document			
	DD	Weinstock et al., "Binding of gastrin(17) to human gastric carcinoma cell lines" Cancer Res., 48(4):932-937, (1988).			
	DE	Wendlberger et al., "The syntheses of human big gastrin I and its 32-leucine analog", Chemical Abstracts 92(21):722 [Abstract #92:198749s].			
	DF	Yamaguchi et al., "Amino-terminal immunoreactivity of big gastrin in plasma and tumors obtained from patients with Zollinger-Ellison Syndrome" Chem. Abstracts 100:373 (1984) [Abstract #100:154661m].			

Examiner Signature	Date Considered
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